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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,966	12/05/2001	Wesley H. Verkaart	70869-0083	1396

7590

09/17/2003

Clark & Brody  
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1750 K Street, NW  
Washington, DC 20006

EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 09/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/001,966	<b>Applicant(s)</b> VERKAART ET AL.	
	<b>Examiner</b> Sandra Saucier	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-11 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

Claims 1-11, 21-23 are pending and are considered on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections – 35 USC § 112***

Claims 1-11, 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Red cells do not have a hematocrit. Blood has a hematocrit, which is the percentage of whole blood volume which is a packed red cell volume as determined by a standard method. The claims are unclear because they do not appear to be scientifically correct.

The term, hematocrit, should not be capitalized. It is neither a proper noun nor a trade name.

**New Matter**

Claims 1-11, 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The new matter inserted appears to be :

a "sterile" washing fluid,

Please point to the place in the specification where the phrase "a sterile washing fluid" is supported.

Insertion of the limitation, sterile washing fluid, has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limitation which would show possession of the concept of the use of a sterile washing fluid. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Thus, the insertion of "sterile washing fluid" is considered to be the insertion of new matter for the above reasons.

Please cancel "sterile".

***Claim Rejections – 35 USC § 103***

Claims 1–11, 21–23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,879,318 [IDS] in combination with US 4,111,199 [A]

The claims are directed to a method for separating red cells having a hematocrit about 30–64 from a solution comprising blood (having a hemocrit about 30–64), anticoagulant and a (sterile) washing solution (starch), whereby the anticoagulant is inert (CPD or heparin) by sedimentation in the absence of centrifugation.

The references are relied upon as explained below.

US 5,879,318 discloses a composition comprising blood, CPD and a rouleaux reagent comprising Hetastarch (col. 5, l. 48, and col. 6, l. 20–29 and claim 3. The HES solution is 6% ( col. 3, l. 21). The blood/anticoagulant 7:1 mixture (col. 5, l. 47) is mixed with the starch and the red cells sedimented (col. 6, l. 1–9) and the supernatant containing the white cells is removed (col. 5, l. 31–38). US 5,879,318 further teaches the use of heparin among other anticoagulants and exemplifies CPD as the anticoagulant of choice in a composition comprising blood, anticoagulant and HES (col. 4, l. 44). The use of

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a short centrifuge spin red cells aids in the sedimentation of the red cells (col. 2, l. 26). However, this is an optional aid in the sedimentation process. Thus, the reference teaches both sedimentation under gravity alone and aided by mild centrifugation.

US 4,111,199 disclose in column 6, the approximate length of time that it takes to allow red cells to sediment under gravity. As is apparent from the examination of the data, the time required depends on the container configuration and on the concentration of HES.

It would have been obvious to use heparin as an anticoagulant in a ratio of 1/7 in a process of adding HES, preferably between 1-6% (col. 4, l. 40) and forming a mixture of blood, heparin 7/1 and 6% HES in order to sediment red cells because '318 generically teaches this method in the absence of unexpected results.

It would have been obvious to allow the red cells to sediment by gravity for about 20 minutes when '318 was taken with '199 because '199 discloses that the length of time for gravity sedimentation of red cells is in the range of 9 to 30 minutes depending on the configuration of the container and on the final concentration of HES.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the resulting composition as suggested by the reference with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

### ***Response to Argument***

Applicant's arguments filed 7/3/03 have been fully considered but they are not persuasive.

Applicants argue that the use of ACD as an anticoagulant renders the use of a gravity sedimentation method of red cell separation unreliable. This may be true, but applicants have not presented any evidence of such unreliability. In fact, US 4,111,199 used ACD as the anticoagulant and then presents data showing that effective gravity separation of red cells is effected with HES over a range of concentrations. The length of time required varies most with the type of container used. Thus, applicants' arguments are unpersuasive because they are not supported by evidence.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (703) 308-4742. The

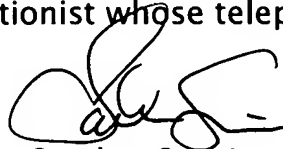
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fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', is positioned above the printed name.

Sandra Saucier  
Primary Examiner  
Art Unit 1651